

2. RESPONSE

2.1 STATUS OF THE CLAIMS

Claims 1-17, 20-50 and 59-84 were pending at the time of the instant Action.

Claims 27-50, 62-63, and 73-82 were previously indicated as allowable in the prior Actions and in the Examiner Interview.

Claims 83 and 84 have been indicated as allowable in the present Action.

No claims have been cancelled herein.

No claims are amended herein.

Claims 85 and 86 are added herein.

Claims 1-17, 20-50, and 59-86 are now pending in the case.

2.2 SUPPORT FOR THE CLAIMS

Support for each of the claims as amended herein is provided by the Specification, drawings, and original claims as filed. Applicants certify that no new matter has been introduced as a result of the accompanying amendment. Specific support for the language of new claims 85 and 86 may be found in presently allowable claims 83 and 84, and in the Specification, at least on pages 11, 13, and 19.

2.3 PREVIOUSLY ALLOWED SUBJECT MATTER

Method claims 27-50, 62-63, and 73-82 and composition claim 72 were previously indicated as allowable by the Examiner in prior Actions and in the Examiner Interview.

Applicants are perplexed by the incongruities of the present Action with respect to already allowable subject matter. In the prior Action, all method claims (claims 27-50 and 73-

82) were previously indicated as allowable, and this was confirmed in the Examiner Interview conducted by Applicants' representative in the Office last year. Examination of the Interview Summary for 14 July 2004 indicates that "agreement was reached" and that the only issues remaining were discussion of "adding concentrations of active compounds to composition claims to remove art rejections." There was no indication in the Interview, or in the written interview summary record that the pending method claims were not allowable.

Likewise, independent composition claim 72 was also previously indicated as allowable. The prior Action was clearly in error when it stated that these claims "would be allowable if rewritten in independent form....." since method claims 27, 73, 74, 77, and 80 and composition claim 72 *are already* in independent form. Therefore, Applicants conclude that the present Action merely contains a typographical error when it states on page 3 that claims 27-50, 62-63, and 72-82 are "objected to for reasons of record," and that the Examiner still considers claim 72, and method claims 27-50, 62-63, and 73-82 to be allowable.

Claims 83 and 84 have been indicated as allowable in the present Action.

Applicants appreciate the indication by the Examiner that claims 83 and 84 are also now allowed.

2.4 THE 35 U. S. C. § 103 REJECTION OF CLAIMS 1-17, 22-26, 59-61, AND 68-71 IS IMPROPER

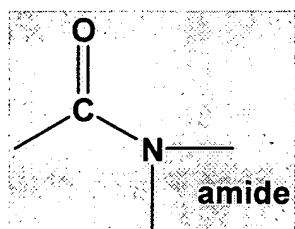
2.4.1 "AMIDES" AND "AMINES" ARE NOT THE SAME CLASS OF CHEMICAL COMPOUNDS

Despite the remarks of Applicants' response to the previous Action, the Office maintains the present rejection based on the fact that the Examiner considers that "amines" and "amides" are chemically the same, and that "nomenclature wise (*sic*) the names" N-acylethanolamides and

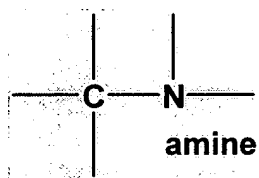
N-acylethanamines “are interchangeable” (Action page 2, section a). As evidence of this supposition, the Examiner provides Applicants a copy of an STN search that appears to *list a number of different compounds* some of which are amides and some of which are amines in the same document record. This database search result provided to Applicants forms the basis of the present rejection, but *in no way* scientifically (or otherwise) *provides any proof* that amines and amides are equivalent. The Office appears to take the position that because these keywords are all *present* in the cited reference, that they are somehow equivalent, or synonymous terms.

While the two words may look similar (differing by a single letter) it is as erroneous to consider them “equivalent” just as it would be to consider chemicals of the class “alkanes” and chemicals of the class “alkynes” to be equivalent merely because the words appear similar.

Applicants state again for the record that amides and amines are TWO DISTINCT CLASSES of chemical compounds. The same way that “aldehydes” and “ketones” are not the same classes of compounds, have different methods of synthesis, and different physical, chemical, and spectral properties (to name only a few of their differences), neither are “amides” and “amines” the same classes of compounds. Amides and amines also have different methods of synthesis, and different physical, chemical, and spectral properties. It is well known in the organic chemical arts that an “amide” has its nitrogen atom bonded to a *carbonyl group*, while an “amine” has its nitrogen atom bonded *only to hydrogen or carbon atoms*. For illustration:



- Nitrogen attached to a carbonyl group (C doubly-bonded to oxygen), the functional group is an amide.
-



Nitrogen attached to a non-carbonyl group C and one or more hydrogen atoms.

One of the most important differences between amine nitrogen and amide nitrogen is that the amine nitrogen is basic, while the amide nitrogen is neutral. This gives rise to fundamentally different chemical properties of these two distinct classes of compounds.

Applicants invite the Office to consult a standard college organic chemistry text, and it will be readily apparent that the Office is improperly interchanging the terms "amine" and "amide", and that compounds of the family "N-acylethanolamines" are quite different physically and chemically from compounds of the family "N-acylethanolamides." To facilitate clarity in this regard, Applicants have taken the liberty of attaching an exhibit that clearly and unambiguously demonstrates that these chemicals are of entirely different chemical classes.

Since the Office has produced no relevant art to support its conclusion that: (a) the terms "amides" and "amines" are synonymous and interchangeable; (b) that the terms "N-acylethanolamines" and "N-acylethanolamides" are likewise synonymous and interchangeable, and (c) these facts provide the proper legal basis for maintaining an obviousness rejection of the claims in view of cited art that discloses certain medicinal uses of compounds of the "N-acylethanolamide" family, when Applicants' invention concerns horticultural formulations and uses of compounds of the "N-acylethanolamine" family, Applicants must conclude that the Examiner is relying on some facts that must lie only within the personal knowledge of an employee of the Office. As such, pursuant to 37 C. F. R. §1.104(d)(2), Applicant hereby request that such a conclusion "be supported by the filing on a affidavit of such employee, and that such

an affidavit be subject to contradiction or explanation by the affidavits of the applicant and other persons.”

In the alternative, Applicant respectfully requests that the obviousness rejections with respect to all claims be withdrawn; and that the case proceed to allowance.

2.4.2 THE OBVIOUSNESS REJECTIONS ARE FACTUALLY IN ERROR

It is well-established that a finding of obviousness under 35 U. S. C. § 103 requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. John Deere Co.*, 148 USPQ 459 (U.S. S.Ct. 1966).

The relevant inquiry is whether the prior art suggests the invention and whether the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 7 USPQ 2d 1673 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success *must be founded in the prior art* and not in the Applicant's disclosure (emphasis added) *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

Therefore, for the cited combination of references to render the present claims legally obvious under 35 U. S. C. § 103, the references must teach or suggest, either alone or in combination, the particular claimed compositions of the present invention. Respectfully, Applicants assert that the cited references do not.

Because of the misperception of the equivalence of the chemical species of the family “amides” and chemical species of the family “amines”, the present obviousness rejections are

fundamentally flawed, and cannot stand. The use of references that relate to one class of chemical compounds, cannot merely be substituted or interchanged to obviate claims to entirely different classes of chemical compounds. To do so would be repugnant to a practitioner in the chemical arts, who readily understands and appreciates the myriad of chemical and physical property differences between disparate classes of chemicals.

Della Valle describes pharmaceutical compositions comprising N-acylethanolamides for the treatment of psoriasis. (1) *Della Valle does not disclose any n-acylethanolamine compounds;* (2) *Della Valle does not disclose any horticultural formulations or uses of the disclosed compounds in the plant arts;* (3) *Della Valle does not provide any motivation to combine the teachings of the reference with any other cited references to arrive at the present invention. Della Valle does not teach or suggest horticultural compositions that comprise at least one N-acylethanolamine, a plant hormone and a horticulturally acceptable vehicle. Della Valle does not provide any motivation to combine its teachings with any of the other cited references to render obvious claim 1, which provides an N-acylethanolamine “in an amount of from about 0.1 micromolar to about 1000 micromolar, said amount effective to prolong the freshness or the aesthetic appearance of a plant, a flower, a fruit, or a plant cutting.”*

The secondary reference Oden is said to teach pharmaceutical compositions comprising gibberellins for use in methods of treatment for prostatitis, and other disease of the prostate in humans. (1) *Oden does not disclose any n-acylethanolamine compounds;* (2) *Oden does not disclose any horticultural vehicles;* (3) *Oden does not provide any motivation to combine the teachings of the reference with any other references to arrive at the present invention, namely horticultural compositions that comprise at least one N-acylethanolamine, a plant hormone and a horticulturally acceptable vehicle. Oden certainly does not provide any motivation to combine*

its teachings with any of the other cited references to render obvious claim 1, which provides an N-acylethanolamine “in an amount of from about 0.1 micromolar to about 1000 micromolar, said amount effective to prolong the freshness or the aesthetic appearance of a plant, a flower, a fruit, or a plant cutting.”

As previously stated in the prior Action response, the addition of the secondary reference, Kemp, is also irrelevant with respect to allegedly obviating the present claims. Kemp describes bath additives containing “aqueous solution of a mixture of amphoteric, anionic, and nonionic substances having a base of a vegetable and/or animal oil and an alcoholic solution having a base of one or more medicinal plants.” The bath additive compositions of Kemp are said to be useful as “agent for the treatment of microbially-induced as well as chronically endogenous skin diseases” in humans. *Kemp teaches or suggest nothing about the preparation of horticultural formulations, or the formulation of any particular N-acylethanolamine compounds “in an amount of from about 0.1 micromolar to about 1000 micromolar” nor does it teach anything about the use of such compounds for preserving the freshness of cut flowers or plant parts.*

None of the cited references discloses or suggests, alone or in combination, the subject matter of independent claim 1, or the composition of any one of claims 64 or 70-72.

Likewise, *there is also absolutely no teaching or suggestion in ANY of the cited references* with respect to the kit claim, claim 26, which recites “A kit comprising the composition of claim 1, and instructions for using said kit to delay the senescence of said plant, flower, fruit, or plant cutting.” Applicants again invite the Office to provide specific examples of the passages used from each of these references to arrive at the legal standard for obviousness, particularly with respect to the element “instructions for using said kit to delay the senescence of said plant, flower, fruit, or plant cutting.”

The Action on page 2, section (b) states that “Examiner argues that where the prior art suggests the claimed invention except for the amount or concentration, it is critical that the Applicant provides a showing to the criticality of the amount/concentration being claimed.”

Applicants have provided an entire range of working examples, exemplified in section 5, as well as at least 10 figures and brief descriptions thereof, showing actual plant cuttings that have been preserved by the illustrative horticultural compositions described in the Specification. Applicants have also provided exhaustive teaching in the Specification (particularly at pages 6-11, 12-15, and 17-19) that describes particularly preferred compositions and “amount/concentration” being claimed. An exemplary commercial formulation of the invention referred to as NF20-XL, is described in Section 2.3 of the Specification, which lists specific formulations of each of the ingredients of the horticultural compositions. Pages 17-19 of the Specification also detail specific ranges of the ingredients of the claimed horticultural compositions that are preferred, highly preferred, and particularly preferred for practice of the present invention.

Applicants respectfully conclude that as a matter of fact, the advanced obviousness rejection is improper, and requests that it be withdrawn.

2.4.3 THE OBVIOUSNESS REJECTION OF THE PENDING CLAIMS IS IMPROPER AS A MATTER OF LAW.

Because the claims in the case particularly point out the distinct features of the inventive methods disclosed in the Specification, and because each of such claims is clearly distinguished over the previously cited art (either alone or in combination) Applicants contend that, as a matter of law, the rejection advanced under 35 U. S. C. § 103 cannot stand.

Applicants again urge the application of the legal standard held in the case of *In re Vaeck*, 20 U.S.P.Q. 1438 (Fed. Cir. 1991), in which the Federal Circuit stated that in order for an examiner to make out a *prima facie* case of obviousness two things must be shown:

- (1) That the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention; and
- (2) That the prior art must demonstrate a reasonable expectation of success of the invention.

Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicant's disclosure (emphasis added).

Furthermore, in the case of *In re Dow Chemical Co.* (837 F. 2d 469, 5, U.S.P.Q.2d 1529, Fed. Cir. 1988) the court held that an “obvious-to-experiment” standard is not an acceptable alternative for obviousness, and that there must be a reason or suggestion in the art, *other than* the knowledge learned from the Applicant's disclosure.

In the instant case, however, there is neither the suggestion nor the reasonable expectation of success. Even if one could somehow postulate that one or more of the cited references might suggest one or more of the individual components of the claimed compositions, might, in an abstract sense, be *plausible*, there is certainly no teaching or suggestion as to how one would go about developing the particular compositions as claimed in the present invention, nor is there any suggestion in the cited references, either alone or in combination, that such an approach would be successful. These references either alone or in combination do not provide the motivation or the teaching for preparing compositions that comprise:

- (a) at least a first compound of the formula:



wherein R is optionally branched or straight chain, saturated or unsaturated C₈-C₂₀ alkyl, in an amount of from about 0.1 μM to about 1000 μM;

- (b) at least a first plant hormone selected from the group consisting of an auxin, a gibberellin and a cytokinin; and
- (c) a horticulturally-acceptable vehicle.

Likewise *there is no motivation or teaching* that such compositions could be used to effect prolonged freshness or aesthetic appearance of a plant, a flower, a fruit or a plant cutting, *nor do these references teach the particular surprising and unexpected results for achieving such prolonged freshness and prolonged aesthetic appearance of plants or plant parts.*

As argued previously, Applicants again submit that the combination of references relied upon by the Examiner also clearly fails to satisfy the tripartite test of *In re O'Farrell* (7 U.S.P.Q.2d 1673, 1680, Fed. Cir. 1988). In *O'Farrell*, the Court held that in order for a reference or references to obviate an invention, it must be shown that the reference(s) contains:

- (1) Detailed enabling methodology for practicing the claimed invention;
- (2) A suggestion for modifying the prior art to practice the claimed invention; and
- (3) Evidence suggesting that the invention would be successful.

In the present case, none of these references provides any teaching relevant to the question of how one of skill in the horticultural arts would be motivated to prepare *N*-acylethanolamine-based compositions that comprise amount of from about 0.1 μM to about 1000 μM; said amount effective to prolong the freshness or the aesthetic appearance of a plant,

a flower, a fruit or a plant cutting; at least a first plant hormone selected from the group consisting of an auxin, a gibberellin and a cytokinin; and,)a horticulturally-acceptable vehicle.

The cited references relied upon by the Office relate to compositions for the treatment of prostate disorders, bath salts for treating skin disorders, and amide-based compositions for treating psoriasis. They *most certainly do not provide* any “detailed enabling methodology” for practicing the claimed invention that relates to N-acylethanolamine-based horticultural compositions for application to plant cuttings and flowers to preserve freshness and to delay senescence.

Also in the present case, none of the cited references provides any suggestion for combining the teachings of, *e.g.*, Della Valle *et al.*, Kemp *et.al*, and/or Oden *et al.* in any combination, or for modifying any of these prior disclosures in a manner that would allow one to arrive at the present invention.

None of the cited references provides any teaching or suggesting that the particular horticultural formulations of the present invention would be successful in any methods involving flower preservation, or the delay of senescence in severed plant parts.

Clearly the rejection is improper as it fails the tripartite test of *In re O'Farrell*.

The Federal Circuit in *Amgen v. Chugai Pharmaceutical Co. Ltd.*, (927 F. 2d 1200, 18 U.S.P.Q. 2d 1016, 1022, Fed. Cir. 1991) affirmed that obviousness under 35 U. S. C. § 103 is a question of law, and that both the suggestion and the expectation of success must be founded in the prior art, and not in the Applicant's disclosure. Because the suggestion and expectation of success are absent in the cited art, Applicants maintain their position that the obviousness rejection of record clearly fails the test set forth by the Court in *Amgen v. Chugai Pharmaceutical Co. Ltd.*

Therefore, as a matter of both fact and law, Applicants believe that the obviousness rejection over these references, either alone, or in any combination, is improper and must be withdrawn. Applicants again respectfully submit that the instant 35 U. S. C. § 103 rejections have been overcome and withdrawal of the rejections is earnestly solicited.

2.5 REQUEST FOR EXAMINER INTERVIEW

Owing to the perplexing position maintained by the Office in the present Action with respect to the obviousness rejections of record, and the significant contradiction of well-known fundamentals of organic chemistry, pursuant to M. P. E. P. § 713.01 and 37 C. F. R. § 1.133, Applicant hereby formally requests the scheduling of an Interview with the Examiner-in-Charge, the Examiner's Supervisory Patent Examiner, and Applicants' undersigned representative to discuss the claims as are now in condition for allowance, and to address any particular remaining issues in the mind of Examiner Pryor once he has had the opportunity to review this response.

2.6 REQUEST FOR ISSUANCE OF NOTICE OF ALLOWABILITY

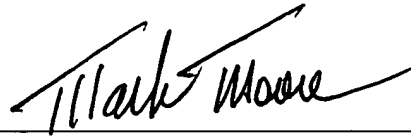
To facilitate a timely and cost-saving conclusion of prosecution on the merits, Applicants respectfully request that the Examiner, mindful of the small-entity status of Applicants, consider the remarks herein, in an effort to secure allowance of the pending claims. Likewise, in the interest of preservation of patent-term and economic considerations of the cost of additional prosecution expenses, Applicants earnestly solicit the concurrence of the Examiner that the remaining issues have been completely resolved to the Office's satisfaction, and request that a Notice of Allowability be entered into the record.

3.0 CONCLUSION

In conclusion, in light of the foregoing remarks, Applicants believe that the concerns set forth in the Action have now been overcome and that all pending claims are in condition for immediate allowance. Such favorable action is respectfully requested. Should the Examiner have any questions concerning the accompanying amendment, response and related papers, a telephone call to the undersigned Applicants' representative would be appreciated.

Respectfully submitted,

WILLIAMS, MORGAN & AMERSON
CUSTOMER NO. 23720

A handwritten signature in black ink, appearing to read "Mark D. Moore", is written over a horizontal line.

Date: March 11, 2005

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